



General

Guideline Title

Monitoring of nonsteroidal immunosuppressive drugs in patients with lung disease and lung transplant recipients: American College of Chest Physicians evidence-based clinical practice guidelines.

Bibliographic Source(s)

Baughman RP, Meyer KC, Nathanson I, Angel L, Bhorade SM, Chan KM, Culver D, Harrod CG, Hayney MS, Highland KB, Limper AH, Patrick H, Strange C, Whelan T. Monitoring of nonsteroidal immunosuppressive drugs in patients with lung disease and lung transplant recipients: American College of Chest Physicians evidence-based clinical practice guidelines. Chest. 2012 Nov;142(5):e1S-e111S. [596 references] PubMed

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

The grades of recommendation (1A, 1B, 1C, 2A, 2B, 2C) are defined at the end of the "Major Recommendations" field.

Monitoring of Nonsteroidal Immunosuppressive Drugs in Patients with Lung Disease and Lung Transplant Recipients

Anti-Tumor Necrosis Factor-α (TNF-α) Agents

For patients who will undergo anti-TNF- α therapy, a chest radiograph is recommended prior to treatment (Grade 1C).

For patients who will undergo anti-TNF- α therapy, a tuberculin skin test is recommended to screen for latent tuberculosis (TB) prior to treatment (Grade 1C).

For patients who will undergo anti-TNF- α therapy and present with a chest radiograph consistent with prior TB or a positive tuberculin skin test and/or are high-risk individuals, active TB infection should be excluded prior to treatment with adalimumab (Grade 1C), etanercept (Grade 1B), or infliximab (Grade 1B).

For patients with latent $Mycobacterium\ tuberculosis$, active prophylactic treatment following published guidelines before initiation of anti-TNF- α therapy is recommended (Grade 1B).

For patients with latent M tuberculosis who will undergo anti-TNF- α therapy, close monitoring for TB is recommended for up to 6 months after discontinuing therapy (Grade 1C).

For patients who develop symptoms indicative of TB, prompt evaluation for active disease is recommended (Grade 1C).

For patients with known grade III or IV New York Heart Association class heart failure, administration of adalimumab (Grade 1C), etanercept (Grade 1C), and infliximab (Grade 1B) is not recommended.

For patients with a history of congestive heart failure (CHF) who undergo anti-TNF- α therapy, close observation for CHF exacerbation is recommended (Grade 1C).

For patients with a history of demyelinating disease, administration of etanercept is not recommended (Grade 1C), and administration of adalimumab and infliximab is not suggested (Grade 2C).

For patients with no history of demyelinating disease who undergo anti-TNF- α therapy and experience symptoms or display signs of a demyelinating process, discontinuation of therapy is suggested (Grade 2C).

For patients who undergo anti-TNF- α therapy and develop symptoms of a lupus-like disorder, discontinuation of therapy is suggested (Grade 2C).

For patients who will undergo anti-TNF- α therapy and who are at risk for viral hepatitis, serologic screening for hepatitis B is recommended prior to treatment (Grade 1C).

For patients who have hepatitis B virus infection, anti-TNF- α therapy should not be administered (Grade 1C).

For patients who undergo anti-TNF- α therapy and develop unresolved infections, discontinuation of treatment until the infection is resolved is recommended (Grade 1B).

For patients who are pregnant, administration of anti-TNF-α therapy is used only if alternatives are not able to be used (Grade 2C).

Calcineurin Inhibitors (CNIs)

For patients who will undergo CNI therapy, the monitoring of drug concentrations, blood pressure (BP), glucose, potassium, magnesium, lipids, complete blood count (CBC), and renal function is recommended (Grade 1B).

For patients who undergo CNI therapy, monitoring of drug levels when hepatic cytochrome P450 system (CYP3A4) inducers or inhibitors are added or stopped and adjusting doses is recommended when using cyclosporin A (Grade 1A) or tacrolimus (Grade 1B) therapy.

For lung transplant recipients receiving CNI therapy who develop renal dysfunction, a reduction in the target dose concentration is suggested (Grade 2C).

Antilymphocyte Antibodies

For patients who undergo antilymphocyte antibody therapy, monitoring for infusion reactions is recommended (Grade 1B).

For patients who undergo antithymocyte globulin or muromonab therapy, monitoring of CBC counts and liver function tests is recommended during therapy (Grade 1B).

For patients with lung disease and lung transplant recipients who will undergo antithymocyte globulin or muromonab therapy, laboratory evaluation for host antibodies (where available) before reinstitution of therapy is suggested (Grade 2C).

For patients who undergo muromonab therapy, monitoring for pulmonary edema and systemic inflammatory response syndrome during therapy is recommended (Grade 1B).

Interleukin 2 (IL-2) Receptor Antagonists

For patients who undergo IL-2 receptor antagonist therapy, monitoring for infusion reactions is recommended (Grade 1C).

For patients who undergo IL-2 receptor antagonist therapy, monitoring of renal function, CBC counts, and infection is recommended (Grade 1C).

For patients who undergo IL-2 receptor antagonist therapy, the simultaneous use of either basiliximab (Grade 1C) or daclizumab (Grade 1B) with antilymphocyte antibodies is not recommended.

Cytotoxic Agents

For patients who will undergo concurrent therapy with azathioprine and allopurinol, a reduction in dose of azathioprine is recommended (Grade

For patients who undergo azathioprine therapy, obtaining CBC counts and renal/hepatic profiles every 1 to 3 months is recommended (Grade 1B).

For patients who will undergo cyclophosphamide therapy, monitoring of CBC count, renal profile, and urinalysis at least monthly for dose adjustment is recommended (Grade 1B).

For patients who will undergo cyclophosphamide therapy, increased fluid intake (e.g., 2 L in addition to normal intake in adults; additional volume given to children needs to be calculated on the basis of body weight) on the days of therapy is recommended (Grade 1C).

For patients who undergo or have undergone cyclophosphamide therapy and develop hematuria, further evaluation is recommended (Grade 1B).

For patients who will undergo leflunomide or methotrexate therapy, screening for the use of alcohol and chronic viral hepatitis prior to treatment is recommended (Grade 2C).

For patients who undergo methotrexate or leflunomide therapy, performance of liver function tests and CBC counts is recommended (Grade 1C).

For patients who undergo methotrexate therapy, folic acid supplementation is recommended (Grade 1A).

For patients who undergo leflunomide therapy and develop neuropathic symptoms, prompt consideration of discontinuing therapy and washing out with cholestyramine is recommended (Grade 1C).

For patients who undergo methotrexate (Grade 1B) or leflunomide (Grade 1C) therapy and develop new or worsening signs or symptoms of lung disease, further evaluation is recommended.

For patients who undergo methotrexate therapy and develop persistently elevated liver transaminases above their own baseline, cessation of treatment or evaluation by liver biopsy is recommended (Grade 1B).

For patients with renal insufficiency, ascites, or pleural effusions who undergo methotrexate therapy, decreased methotrexate clearance may be present, and dose reduction may be required (Grade 2C).

For patients who undergo mycophenolic acid therapy and develop adverse gastrointestinal (GI) affects, including diarrhea, interruption of therapy or reduction in dose is recommended (Grade 1B).

For patients who undergo mycophenolic acid therapy and develop signs or symptoms of progressive multifocal leukoencephalopathy, cessation of treatment is suggested (Grade 2C).

Mammalian Target of Rapamycin (mTOR) Inhibitors

For patients who will undergo mTOR inhibitor therapy, obtaining cholesterol and triglyceride levels prior to treatment is recommended (Grade 1B).

For patients who present with an abnormal elevation of fasting triglycerides, avoidance of mTOR therapy or careful monitoring of triglycerides is recommended (Grade 1B).

For patients who undergo mTOR therapy, monitoring for hyperlipidemia is recommended (Grade 1A).

For patients who undergo mTOR therapy, monitoring of CBC counts, creatinine, and BP is recommended (Grade 1B).

For patients who undergo sirolimus therapy, monitoring of drug concentration is recommended (Grade 1B).

For lung transplant recipients scheduled to undergo sirolimus therapy, administration of sirolimus during the early perioperative period is contraindicated due to the risk of airway dehiscence (Grade 1A).

For patients who undergo sirolimus therapy and are at risk for poor wound healing, consideration of dose adjustments or an alternative therapy to lower this risk is suggested (Grade 2C).

For patients who undergo sirolimus therapy and develop new or worsening respiratory symptoms or signs, an evaluation for sirolimus-induced pulmonary toxicity is recommended (Grade 1B).

Other Immunosuppressive Drugs

For patients receiving hydroxychloroquine and chloroquine, an eye examination at least once per year is suggested (Grade 2B).

For patients who undergo imatinib mesylate therapy, monitoring of CBC and hepatic function is suggested (Grade 2C).

<u>Definitions</u>:

Strength of the Recommendations Grading System

Grade of Recommendation*	Benefit vs. Risk and Burdens	Methodologic Quality of Supporting Evidence	Implications
Strong recommendation, high-quality evidence, Grade 1A	Benefits clearly outweigh risk and burdens or vice versa	Consistent evidence from randomized controlled trials (RCTs) without important limitations or exceptionally strong evidence from observational studies	Recommendation can apply to most patients in most circumstances. Further research is very unlikely to change confidence in the estimate of effect
Strong recommendation, moderate-quality evidence, Grade 1B	Benefits clearly outweigh risk and burdens or vice versa	Evidence from RCTs with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence from observational studies	Recommendation can apply to most patients in most circumstances. Higher quality research may well have an important impact on confidence in the estimate of effect and may change the estimate
Strong recommendation, low- or very-low- quality evidence, Grade 1C	Benefits clearly outweigh risk and burdens or vice versa	Evidence for at least one critical outcome from observational studies, case series, or from RCTs with serious flaws or indirect evidence	Recommendation can apply to most patients in many circumstances. Higher-quality research is likely to have an important impact on confidence in the estimate of effect and may well change the estimate
Weak recommendation, high-quality evidence, Grade 2A	Benefits closely balanced with risks and burden	Consistent evidence from RCTs without important limitations or exceptionally strong evidence from observational studies	The best action may differ depending on circumstances or patient or society values. Further research is very unlikely to change confidence in the estimate of effect
Weak recommendation, moderate-quality evidence, Grade 2B	Benefits closely balanced with risks and burden	Evidence from RCTs with important limitations (inconsistent results, methodologic flaws, indirect or imprecise) or very strong evidence from observational studies	Best action may differ depending on circumstances or patient or society values. Higher-quality research may well have an important impact on confidence in the estimate of effect and may change the estimate
Weak recommendation, low- or very-low- quality evidence, Grade 2C	Uncertainty in the estimates of benefits, risks, and burden; benefits, risk, and burden may be closely balanced	Evidence for at least one critical outcome from observational studies, case series, or RCTs, with serious flaws or indirect evidence	Other alternatives may be equally reasonable. Higher-quality research is likely to have an important impact on confidence in the estimate of effect and may well change the estimate

^{*}The guideline developers use the wording recommend for strong (Grade 1) recommendations and suggest for weak (Grade 2) recommendations.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Diffuse interstitial, inflammatory lung disease (e.g., sarcoidosis, pulmonary vasculitis, idiopathic interstitial pneumonia)
- Lung transplantation

Guideline Category

Management

Treatment

Clinical Specialty

Internal Medicine

Pulmonary Medicine

Thoracic Surgery

Intended Users

Physicians

Guideline Objective(s)

- To provide recommendations for monitoring the use of immunosuppressive drugs so that clinically significant side effects can be either avoided or recognized in a timely fashion
- To achieve maximal patient safety when these nonsteroidal immunosuppressive medications are prescribed

Note: This guideline does not provide recommendations concerning indications for use of these drugs.

Target Population

- · Patients with diffuse interstitial or inflammatory lung disease
- Lung transplant recipients

Interventions and Practices Considered

- 1. Anti-tumor necrosis factor- α (TNF- α) agents (adalimumab, etanercept, infliximab)
 - Screening for latent tuberculosis (TB) infection (tuberculin skin test)
 - Chest radiograph
 - Assessment of New York Heart Association class heart failure
 - Serologic screening for hepatitis B
 - Close observation of patients with a history of congestive heart failure for exacerbation
 - Active prophylactic treatment of patients with latent TB
 - Close monitoring of patients with latent TB for signs of active disease
 - Evaluation of patients for active TB
 - Discontinuation of TNF-α agents in patients with unresolved infections or other comorbid conditions
 - Administration of TNF-α agents during pregnancy
- 2. Calcineurin inhibitors (CNIs)
 - Monitoring of drug concentrations, blood pressure (BP), glucose, potassium, magnesium, lipids, complete blood count (CBC) count, and renal function
 - Dose adjustment (as indicated)
- 3. Antilymphocyte antibody therapy

- Monitoring for infusion reactions
- Antithymocyte globulin or muromonab therapy (monitoring of CBC counts, liver function tests)
- 4. Interleukin-2 (IL-2) receptor antagonist therapy
 - Monitoring for infusion reactions (monitoring of renal function, CBC counts, and infection is recommended)
- 5. Cytotoxic agents
 - Azathioprine therapy (monitoring CBC counts and renal/hepatic profiles, laboratory evaluation for host antibodies, monitoring for pulmonary edema)
 - Cyclophosphamide therapy (monitoring of CBC count, renal profile, and urinalysis, increased fluid intake)
 - Further evaluation of patients treated with cyclophosphamide therapy who develop hematuria
 - Leflunomide or methotrexate
 - Screening for the use of alcohol and chronic viral hepatitis prior to treatment
 - Liver function tests and CBC counts
 - Folic acid supplementation (as indicated)
 - Consideration of discontinuing leflunomide therapy and washing out with cholestyramine for neuropathic symptoms
 - Monitoring for and further evaluation of signs or symptoms of lung disease
 - Cessation of methotrexate treatment and evaluation by liver biopsy for persistently elevated liver transaminases
 - Adjustment in methotrexate dose in patients with renal insufficiency, ascites, or pleural effusions
 - Mycophenolic acid therapy (interruption of therapy or reduction in dose for adverse events, cessation of therapy for signs or symptoms of progressive multifocal leukoencephalopathy)
- 6. Mammalian target of rapamycin (mTOR) inhibitors
 - Cholesterol and triglyceride level measurements prior to treatment
 - Monitoring for hyperlipidemia, CBC counts, creatinine, and BP
 - Sirolimus therapy (monitoring of drug concentration, evaluation for sirolimus-induced pulmonary toxicity)
- 7. Immunosuppressive drugs
 - Hydroxychloroquine, chloroquine (eye examination at least once per year)
 - Imatinib mesylate (monitoring of CBC and hepatic function)

Note: Anti-TNF- α therapy in patients with grade III or IV New York Heart Association class heart failure, a history of demyelinating disease, or hepatitis B virus infection was considered but not recommended. In IL-2 receptor antagonist therapy, the simultaneous use of either basiliximab or daclizumab with antilymphocyte antibodies is not recommended.

Major Outcomes Considered

- Incidence and severity of
 - Major organ system dysfunction
 - Opportunistic infection
- Mortality because of drug toxicity

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Review of Evidence

The literature review was based on the research questions and inclusion criteria as defined in Tables 1 and 2 of the original guideline document,

respectively. The literature review was conducted through a comprehensive Medline search from 1980 through February 2008 and supplemented by articles supplied by the guideline panel, bibliographies and reference lists from reviewed articles, and other existing systematic reviews. The literature search was initially limited to randomized controlled trials (RCTs), but because of the paucity of data for some drugs, the literature search was expanded to include prospective studies, case series, and systematic reviews. Case reports were also reviewed but not included in any of the evidence tables. The search strategy linked each drug with the key questions presented in Table 1 in the original guideline document and restricted the search to patients with lung disease and lung transplant recipients. To locate studies such as systematic reviews and meta-analyses, the key words were used in Medline and the Cochrane Review databases.

Number of Source Documents

The American College of Chest Physicians (ACCP) clinical research analyst conducted an initial review of >500 abstracts. More than 350 full articles were formally reviewed and abstracted by the clinical research analyst, and >250 studies were included in the evidence tables.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

The strength of evidence is classified into three categories of high (Grade A), moderate (Grade B), and low or very low (Grade C) based on the quality of data. The highest-quality evidence comes from well-designed randomized controlled trials (RCTs) yielding consistent and directly applicable results. In some circumstances, high-quality evidence can be the result of overwhelming evidence from observational studies. Moderate-quality evidence is based on RCTs with some limitations that may include methodologic flaws or inconsistent results. Studies other than RCTs that may yield strong results are also included in the moderate category. The weakest evidence comes from other types of observational studies.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Randomized controlled trials (RCTs) were scored using the Jadad et al. grading system. This system follows a method that is based on a three-point scale that rates randomization (and appropriateness), blinding (and appropriateness), and tracking of withdrawals and losses to follow-up. Studies were graded on a scale of 0 to 5. Study adequacy was then given a score from poor to excellent. Other prospective studies were informally graded on methodology and tracking of patients included in the studies. No formal quantitative analysis was performed because of the wide variety of studies included for each drug. Given the length of time required to prepare the final manuscript after conclusion of the systematic review, the panel included references in the text that were outside the formal review deadline to keep the guideline current. The evidence tables provide a summary of studies performed with individual drugs for organ transplantation and lung disease. These tables became the basis for the specific evidence-based recommendations regarding monitoring. Because of the paucity of evidence for the use of these drugs in lung transplantation, recommendations were based primarily on extrapolated data from other organ transplant studies.

It should be noted that the Health and Science Policy Committee (HSP) endorses the principle that most relevant clinical studies provide evidence, although the quality of that evidence may vary. The minimum threshold for qualifying evidence, per HSP policy, is that it must be published in peer-reviewed journals. The balance of benefits to risk and burden and the level of certainty based on this balance are summarized in Table 4 of the original guideline document.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Expert Panel Composition

The guideline panel was organized according to American College of Chest Physicians (ACCP) policy. Membership was obtained through open nomination from the ACCP membership. Panel members were selected based on clinical and methodological expertise and represent a wide range of specialists in this field. The panel met for a 2-day meeting to review the evidence and structure the guideline. All other business was handled through conference calls and electronic means. Writing assignments were determined by panel members' known expertise in the specific drug areas. Each section of the guideline was assigned one primary and one secondary author. In addition, a pediatric expert provided input to sections that were relevant to children's health care.

Grading of Recommendations

The ACCP system for grading guideline recommendations is based on the relationship between the strength of evidence and the balance of benefits to risk and burden (Table 3 of the original guideline document). Simply stated, recommendations can be strong (grade 1) or weak (grade 2). If there is certainty that the benefits do (or do not) outweigh risk, the recommendation is strong. If there is less certainty or the benefits and risks are more equally balanced, the recommendation is weaker. Several important issues must be considered when classifying recommendations. These include the quality of the evidence that supports estimates of benefit, risks, and costs; the importance of the outcomes of the intervention; the magnitude and precision of the estimate of treatment effect; the risks and burdens of an intended therapy; the risk of the target event; and varying patient values. The benefit-to-harm ratio includes consideration of the clinical improvements in health and quality of life as well as the burdens, risks, and costs, when applicable, identifiable, and determinable (Table 3 of the original guideline document). Patient and community values are important considerations in clinical decision-making and are factored into the grading process. In situations where the benefits clearly do or do not outweigh the risks, it is assumed that nearly all patients would have the same preferences. For weaker recommendations, however, there may not be consistency in patient preferences.

Rating Scheme for the Strength of the Recommendations

Strength of the Recommendations Grading System

Grade of Recommendation*	Benefit vs. Risk and Burdens	Methodologic Quality of Supporting Evidence	Implications
Strong recommendation, high-quality evidence, Grade 1A	Benefits clearly outweigh risk and burdens or vice versa	Consistent evidence from randomized controlled trials (RCTs) without important limitations or exceptionally strong evidence from observational studies	Recommendation can apply to most patients in most circumstances. Further research is very unlikely to change confidence in the estimate of effect
Strong recommendation, moderate-quality evidence, Grade 1B	Benefits clearly outweigh risk and burdens or vice versa	Evidence from RCTs with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence from observational studies	Recommendation can apply to most patients in most circumstances. Higher quality research may well have an important impact on confidence in the estimate of effect and may change the estimate
Strong recommendation, low- or very-low- quality evidence, Grade 1C	Benefits clearly outweigh risk and burdens or vice versa	Evidence for at least one critical outcome from observational studies, case series, or from RCTs with serious flaws or indirect evidence	Recommendation can apply to most patients in many circumstances. Higher-quality research is likely to have an important impact on confidence in the estimate of effect and may well change the estimate
Weak recommendation, high-quality evidence, Grade 2A	Benefits closely balanced with risks and burden	Consistent evidence from RCTs without important limitations or exceptionally strong evidence from observational studies	The best action may differ depending on circumstances or patient or society values. Further research is very unlikely to change confidence in the estimate of effect
Weak	Benefits closely	Evidence from RCTs with important	Best action may differ depending on

recommendation, moderate-quality Recommendation* evidence, Grade	balanced with risks and burden Burdens	imitations (inconsistent results Wethodologic Quality of Supporting methodologic flaws, indirect or Evidence imprecise) or very strong evidence from observational studies	circumstances or patient or society values. Higher-quality research may well have an important impact on confidence in the estimate of effect and may change the estimate
Weak recommendation, low- or very-low- quality evidence, Grade 2C	Uncertainty in the estimates of benefits, risks, and burden; benefits, risk, and burden may be closely balanced	Evidence for at least one critical outcome from observational studies, case series, or RCTs, with serious flaws or indirect evidence	Other alternatives may be equally reasonable. Higher-quality research is likely to have an important impact on confidence in the estimate of effect and may well change the estimate

^{*}The guideline developers use the wording recommend for strong (Grade 1) recommendations and suggest for weak (Grade 2) recommendations.

Cost Analysis

A cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Not stated

Description of Method of Guideline Validation

Not applicable

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate management of nonsteroidal immunosuppressive drugs in patients with lung disease with lung transplant recipients

Potential Harms

Patients receiving routine immunosuppressives, including prednisone, may have a false-negative tuberculin skin test, but they will still respond to $Mycobacterium\ tuberculosis$ -specific γ -interferon testing.

Contraindications

Contraindications

- Sirolimus
 - Fasting serum triglyceride level >500 mg/dL
 - For lung transplant recipients scheduled to undergo sirolimus therapy, administration of sirolimus during the early perioperative period
 is contraindicated due to the risk of airway dehiscence.
- Chloroquine
 - Hypersensitivity to drug class or compound components
 - Retinal field changes
 - With topical benzocaine; butamben; tetracaine, lidocaine; prilocaine topical in infants aged <1 y because of risk of methemoglobinemia; pimozide; and ranolazine, which may increase risk of QT prolongation with resulting cardiac dysrhythmias
- Hydroxychloroquine
 - Hypersensitivity to drug class or compound components
 - · Retinal field changes
 - Visual field changes
 - Psoriasis
 - Pregnancy
- Muromonab use is contraindicated during pregnancy and breastfeeding.
- Leflunomide use is contraindicated during pregnancy.
- Use of etanercept or infliximab should be avoided if active viral hepatitis is present.
- Live vaccines should be avoided while patients are being treated with adalimumab, etanercept, infliximab, or mycophenolate.
- Mycophenolate may have teratogenic or embryocidal effects on the fetus, and patients receiving immunosuppressive drugs, including
 mycophenolate, have been advised to avoid pregnancy. Concomitant use of mycophenolate and azathioprine should be avoided.
- Equine antithymocyte globulin (ATG) is contraindicated in patients with a personal history of hypersensitivity to lymphocyte immune globulin, ATGs from horse, or other equine protein products.

Qualifying Statements

Qualifying Statements

American College of Chest Physician (ACCP) guidelines are intended for general information only, are not medical advice, and do not replace professional medical care and physician advice, which always should be sought for any medical condition. The complete disclaimer for this guideline can be accessed at ACCP Web site.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Patient Resources

Quick Reference Guides/Physician Guides

Slide Presentation

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report

Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Safety

Identifying Information and Availability

Bibliographic Source(s)

Baughman RP, Meyer KC, Nathanson I, Angel L, Bhorade SM, Chan KM, Culver D, Harrod CG, Hayney MS, Highland KB, Limper AH, Patrick H, Strange C, Whelan T. Monitoring of nonsteroidal immunosuppressive drugs in patients with lung disease and lung transplant recipients: American College of Chest Physicians evidence-based clinical practice guidelines. Chest. 2012 Nov;142(5):e1S-e111S. [596 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Nov

Guideline Developer(s)

American College of Chest Physicians - Medical Specialty Society

Source(s) of Funding

American College of Chest Physicians (ACCP)

Guideline Committee

American College of Chest Physicians (ACCP) Health and Science Policy Committee (HSP)

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

From the outset, each member completed a conflict of interest (COI) form to be kept on file with the American College of Chest Physicians (ACCP). In addition, panel members updated COI forms at the face-to-face meeting and verbally related any changes in conflict status during conference calls. Final disclosures were collected at the time of submission for publication.

The authors have reported to CHEST the following conflicts of interest: Dr Baughman's institution (University of Cincinnati) has received grants for research in sarcoidosis and idiopathic pulmonary fibrosis from Actelion Pharmaceuticals Ltd; Celgene Corporation; Cephalon, Inc; Centocor Ortho Biotech, Inc; Gilead Sciences, Inc; and InterMune. Dr Hayney has received grant support from the University of Wisconsin and the National Institutes of Health. She serves on the speakers' bureau for Merck Vaccines. Dr Patrick received a travel stipend from Omneotech, Inc; owns stock in pharmaceutical/medical device companies, including Human Economics, Rite Aid Corp, Numec, and Hospira, Inc; and is a member of the speakers' bureau for Gilead Sciences, Inc. Dr Strange has received grant monies and salary support from the National Institutes of Health to study cyclophosphamide and mycophenolate mofetil in scleroderma. He has received grant monies and salary support from Centocor Ortho Biotech, Inc, for the study of ustekinumab and golimumab in sarcoidosis. He has been a consultant for AstraZeneca; Uptake Medical; PneumRx, Inc; Pulmonx; Aeris Therapeutics; Talecris Biotherapeutics Inc; CSL Behring; Baxter; Gilead Sciences, Inc; MedImmune, LLC; and Actelion Pharmaceuticals Ltd in the past 3 years. For the past 3 years, he has received speakers' bureau income from AstraZeneca; Talecris Biotherapeutics, Inc; Gilead Sciences, Inc; Actelion Pharmaceuticals Ltd; and Pfizer, Inc, and from the France Foundation for InterMune on topics not related to the subject of this article. Dr Whelan has received research support from Actelion Pharmaceuticals Ltd; Celgene Corporation; Centocor Ortho Biotech, Inc; and InterMune. He has also received consultant fees from InterMune. His contributions to this article were free from potential conflicts of interest related to these activities. Drs Meyer, Nathanson, Angel, Bhorade, Chan, Culver, Highland, and Limper and Mr Harrod have reported that no potential conflicts of interest exist with any companies/organizations whose products or services may be discussed in this article.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available to subscribers of Chest - The Cardiopulmonary and Critical Care Journal

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348.

Availability of Companion Documents

The following are available:

- Executive summary: monitoring of nonsteroidal immunosuppressive drugs in patients with lung disease and lung transplant recipients: American College of Chest Physicians evidence-based clinical practice guidelines. Chest 2012;142(5):e1S-e111S. Electronic copies: Available to subscribers of Chest The Cardiopulmonary and Critical Care Journal.
- Monitoring of nonsteroidal immunosuppressive drugs in patients with lung disease and lung transplant recipients: American College of Chest Physicians evidence-based clinical practice guidelines. Slide set. Northbrook (IL): American College of Chest Physicians; 2012. 52 p.

Electronic copies: Availal	ble in Portable Document Format ((PDF) from the American	College of Chest Physicians W	leb site

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348.

Patient Resources

The following is available:

 Guide for patients taking nonsteroidal immunosuppressive drugs. Patient education guide. Northbrook (IL): American College of Chest Physicians; 2012. 4 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Chest Physicians Web site

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

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